DSJ1&2-PR Exh 544

From: Clark, Jessica
Sent: Tuesday, October 25, 2016 7:32 AM
To: Poshni, Faiza; Feniger, Angela; Jones, Heather
Cc: Clark, Jessica; Conti, Joan; Dec, John; Shukla, Jaydeep; Brantley, Eric; Roman, Sonia
Subject: RE: SOMs
Attachments: SOP-SO-0002.doc; SOP-SO-0004.doc

Good morning Faiza/Angela/Heather.

I am reviewing SOP's for our department and believe SOP SO-0002 (copy attached) should be retired since SOM is now handled by Eric Brantley in Huntsville.
The SOP does address our department's quarterly DEA audit process, but I would propose to modify SOP SO-004 (copy also attached) to include reference to the DEA audit.

SOP SO-002 also addresses monthly Compliance reporting.
Heather/Angela,
When the transfer of all controlled substances to Huntsville is complete in early November, will you need Joan to provide any controlled substance reporting on a forward basis?

Please review when you can and please provide feedback.

Thank you.

Jessica Clark
Director, Customer Operations
Par Pharmaceutical | Six Ram Ridge Road | Chestnut Ridge, NY 10977
[redacted] | Fax: 201.391.5217
Jessica.Clark@parpharm.com

From: Shukla, Jaydeep
Sent: Monday, April 11, 2016 3:52 PM
To: Clark, Jessica
Cc: Feniger, Angela; Poshni, Faiza
Subject: RE: SOMs

Thank you Jessica!

Jaydeep Shukla | Specialist, DEA Compliance
Par Pharmaceutical | 2 Ram Ridge Road | Chestnut Ridge, NY 10977
[redacted] | jaydeep.shukla@parpharm.com
www.parpharm.com

From: Clark, Jessica
Sent: Monday, April 11, 2016 3:51 PM
To: Shukla, Jaydeep
Cc: Feniger, Angela; Poshni, Faiza
Subject: RE: SOMs

HI Jaydeep,

Yes, we evaluate controlled substance orders based on customer provided usage and/or customer typical purchase patterns.

Jessica Clark
Director, Customer Operations
Par Pharmaceutical Companies, Inc. | Six Ram Ridge Road | Chestnut Ridge, NY 10977
[redacted] | Fax: 201.391.5217
Jessica.Clark@parpharm.com

From: Shukla, Jaydeep
Sent: Thursday, April 07, 2016 11:42 AM
To: Clark, Jessica
Cc: Feniger, Angela; Poshni, Faiza
Subject: SOMs

Hi Jessica,

Is your group evaluating controlled substance orders as per SOP-SO-002 suspicious order monitoring?

Thank you,
Jaydeep

Jaydeep Shukla | Specialist, DEA Compliance
Par Pharmaceutical | 2 Ram Ridge Road | Chestnut Ridge, NY 10977
[redacted] jaydeep.shukla@parpharm.com
www.parpharm.com

PAR PHARMACEUTICAL INC.
STANDARD OPERATING PROCEDURE

Title: SUSPICIOUS ORDER MONITORING (SOM)		
Department: SO		Document No: SOP-SO-0002 Version: 1.6
Legacy Document ID: SO002.1		Page: 1 of 4

Written by:	CoSign Digital Signature
Checked by:	CoSign Digital Signature
Approved by:	CoSign Digital Signature

PAR PHARMACEUTICAL INC.
STANDARD OPERATING PROCEDURE

Title: SUSPICIOUS ORDER MONITORING (SOM)		
Department: SO		Document No: SOP-SO-0002 Version: 1.6
Legacy Document ID: SO002.1		Page: 2 of 4

Table of Contents

PAR PHARMACEUTICAL INC.
STANDARD OPERATING PROCEDURE

Title: SUSPICIOUS ORDER MONITORING (SOM)		
Department: SO		Document No: SOP-SO-0002 Version: 1.6
Legacy Document ID: SO002.1		Page: 3 of 4

I. PURPOSE

Define process of Suspicious Order Monitoring (SOM) for all controlled substances ordered directly by Par Trade Customers via a Purchase Order.

II. POLICY

As determined by Sales Operations with guidance from Quality Compliance ensuring we are in line with DEA requirements.

III. ROLES AND RESPONSIBILITIES

Sales Operations/Account Services to monitor applicable Par Trade Customer Purchase Orders for any notable variations in ordering patterns.

IV. PROCEDURE

Par's Trade customers transmit Controlled Purchase Orders via EDI and minimal Purchase Orders come in via fax/scan-email.

Weekly replenishment Purchase Orders are analyzed by Account Service Executives verses Customer provided usages.
If quantities are higher than the average transmission it is questioned.

The Buyer is contacted to review, a written request is asked as to the reason for the increase.
It is reviewed to ensure it is correct and warranted.

Seasonal changes are monitored if applicable to the product.

PAR PHARMACEUTICAL INC.
STANDARD OPERATING PROCEDURE

Title: SUSPICIOUS ORDER MONITORING (SOM)		
Department: SO		Document No: SOP-SO-0002 Version: 1.6
Legacy Document ID: SO002.1		Page: 4 of 4

Customer Usage grids are created for each controlled drug distributed as a benchmark to monitor Customer Purchase Orders.

Customers may have a change in usage when reported or uncovered grid would then get updated to reflect accordingly.

Controlled Substance product launch

[redacted]

Reporting Suspicious Criminal Activities

If criminal activity is suspected, report the following to the state agencies that licensed the facility (e.g. board of pharmacy) and Food and Drug Administration (FDA), as well as Drug Enforcement Administration (DEA) for controlled substances within three days of suspecting criminal activity.

V. EXTERNAL REFERENCES

Sample of a Customer Usage Letter at Product Launch

VI. REVISION HISTORY

Revision	Description of Changes

Document Could Not Be Rendered

CoSign Digital Signature

CoSign Digital Signature

Document Could Not Be Rendered

CoSign Digital Signature

Document Could Not Be Rendered

E1840.13

PAR PHARMACEUTICAL INC.
STANDARD OPERATING PROCEDURE

Title: PRESCRIPTION DRUG ORDER MONITORING		
Department: SO		Document No: SOP-SO-0004 Version: 1.5
Legacy Document ID: SO004.0		Page: 1 of 4

Deleted:

Written by:	CoSign Digital Signature
Checked by:	CoSign Digital Signature
Approved by:	CoSign Digital Signature

PAR PHARMACEUTICAL INC.
STANDARD OPERATING PROCEDURE

Title: PRESCRIPTION DRUG ORDER MONITORING		
Department: SO		Document No: SOP-SO-0004 Version: 1.5
Legacy Document ID: SO004.0		Page: 2 of 4

Deleted:

Table of Contents

PAR PHARMACEUTICAL INC.
STANDARD OPERATING PROCEDURE

Title: PRESCRIPTION DRUG ORDER MONITORING		
Department: SO		Document No: SOP-SO-0004 Version: 1.5
Legacy Document ID: SO004.0		Page: 3 of 4

Deleted:

I. PURPOSE

Define process of Prescription Drug Order Monitoring for RX drugs ordered directly by Par Trade Customers via a Purchase Order.

II. POLICY

A. As determined by Sales Operations with guidance from Quality Compliance ensuring we are in line with compliance guidelines.

B. If the Prescription Drug Order Monitoring process does not meet the requirements of this SOP and criminal activity or suspicious product is suspected (refer to SOP QA109: Notification process to the Federal and State Agencies (DEA, New York State Board of Pharmacy).

III. ROLES AND RESPONSIBILITIES

Sales Operations/Account Services to monitor applicable Par Trade Customer Purchase Orders for any notable variations in ordering patterns.

IV. PROCEDURE

Par's Trade customers transmit Prescription Drug Purchase Orders via EDI and minimal Purchase Orders come in via fax/scan-email.

Weekly replenishment Purchase Orders are analyzed by Account Service Executives verses Customer provided usages.
If quantities are higher than the average transmission it is questioned.

The Buyer is contacted to review, a written request is asked as to the reason for the increase.
It is reviewed to ensure it is correct and warranted.

Seasonal changes are monitored if applicable to the product.

Customers may have a change in usage when reported tracking docs would then

PAR PHARMACEUTICAL INC.
STANDARD OPERATING PROCEDURE

Title: PRESCRIPTION DRUG ORDER MONITORING		
Department: SO		Document No: SOP-SO-0004 Version: 1.5
Legacy Document ID: SO004.0		Page: 4 of 4

Deleted:

get updated to reflect accordingly.

[redacted]

V. EXTERNAL REFERENCES

QA109 : Notification process to the Federal and State Agencies (DEA, New York State Board of Pharmacy)

VI. REVISION HISTORY

Revision	Description of Changes
	No changes required

CoSign Digital Signature

CoSign Digital Signature

Document Could Not Be Rendered

CoSign Digital Signature

Document Could Not Be Rendered

Document Could Not Be Rendered